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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/925,728	08/10/2001	Peter Geistlich	1194-179	5552

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ROTHWELL, FIGG, ERNST & MANBECK, P.C.
1425 K STREET, N.W.
SUITE 800
WASHINGTON, DC 20005

EXAMINER

PELLEGRINO, BRIAN E

ART UNIT PAPER NUMBER

3738

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/925,728

Applicant(s)

GEISTLICH ET AL.

Examiner

Brian E Pellegrino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 22-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 and 22-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 August 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's after-final amendment filed on 10/15/03 has been entered.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the lack of a "separate hemostatic barrier layer" must be shown or the feature(s) canceled from the claim(s). According to Figures 4 and 4A, it would appear the drawings show separate layers. No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Objections

Claim 22 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper

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dependent form, or rewrite the claim(s) in independent form. The claim does not further limit any claim since it depends from a canceled claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-20,22-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear what applicants mean by the term "separate" layer in claim 1. Claim 1 recites a "multi-layer" sheet with a "barrier layer" and a "matrix layer" and then recites the step of "fixing without application of a separate hemostatic barrier layer" which contradicts the use of multiple layers. If applicants patch is not of separate layers than how can two different collagens be claimed to form a single patch or sheet?

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-6,15,16,18-20,23,24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stone et al. (5624463) in view of Pachence et al. (WO 96/24310). Stone et al. disclose a method of *promoting cartilage regeneration* through the use of a scaffold or matrix, col. 2, lines 50-52. Fig. 9 of Stone shows a barrier layer **12** oriented away from the damaged area in a cavity of a joint and can be made predominately of

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collagen I, col. 7, lines 56,57. Stone also shows the multi-component patch device has the inner component with an open sponge-like texture, Fig. 4B. Stone et al. additionally disclose the inner component or base is also made of collagen and can be collagen II, col. 9, lines 33-35, col. 12, lines 54-56. Stone also discloses that the matrix layer is impregnated with a GAG or hyaluronic acid, col. 3, lines 30-38. Stone discloses the patch or device is fixed to the area of treatment by adhesively bonding to the area, col. 5, lines 41-43. Biologically active substances, such as chondrocytes are charged into the patch, col. 15, lines 43-45. Stone discloses that natural cartilage can be used from pigs to obtain collagen II (inherently hyaline type), col. 8, lines 62,63. The collagen component can be crosslinked, col. 14, lines 29,39. However, Stone et al. do not disclose the inner layer as a membrane or an alternative attachment process, such as suturing the patch to the area of treatment. Pachence et al. teach an inner membrane **14** and sutures **10** to secure a cartilage repair device in place, Fig. 3. It would have been obvious to one of ordinary skill in the art to modify the inner component and use a membrane and sutures as taught by Pachence with the cartilage repair device of Stone such that a smaller area can be treated.

Claims 8,9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stone et al. '463 in view of Pachence et al. (WO 96/24310) as applied to claim 6 above, and further in view of Sonis (WO 90/13302). Stone et al. in view of Pachence et al. is explained supra. However, Stone et al. as modified by Pachence et al. do not disclose the membrane carrying pharmaceutically active substances, such as BMPs. Sonis teaches that BMPs can be used with membranes for tissue regeneration, page 10, lines

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22-31. Table II (page 28) show numerous agents, i.e. PDGF or PTH. It would have been obvious to one of ordinary skill in the art to impregnate the membrane with a pharmaceutically active substance as taught by Sonis in the membrane of Stone et al. in view of Pachence et al. in order to enhance the capabilities of the tissue regeneration process and allow for controlled release of the substances.

Claims 10,11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stone et al. '463 in view of Pachence et al. as applied to claim 1 above, and further in view of Caplan et al. (5197985). Stone et al. in view of Pachence et al. is explained supra. However, Stone et al. as modified by Pachence et al. do not disclose the use of stem cells or stromal cells incorporated in the membrane. Caplan et al. teach that mesenchymal stem cells can be incorporated into carriers or membranes for tissue regeneration, col. 2, lines 6-11,27-34. Caplan also teaches that the stem cells are capable of determining which connective tissue to regenerate, i.e. cartilage, col. 3, lines 20-24,35-45. The cells and carrier is used to repair cartilage of a joint, col. 16, lines 40-53. Caplan additionally teaches that stromal cells from bone marrow can be harvested for use, col. 15, lines 25-28,39-49. It would have been obvious to one of ordinary skill in the art to impregnate the membrane with stem or stromal cells as taught by Caplan et al. in the membrane of Stone et al. in view of Pachence et al. in order to provide enhanced osteogenic activity.

Claims 13,14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stone et al. '463 in view of Pachence et al. as applied to claim 1 above, and further in view of Geistlich et al. (5573771). Stone et al. as modified by Pachence et al. is

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explained supra. However, Stone in view Pachence et al. Pachence do not disclose the use of a bone mineral implanted in the region of the bone injury. Geistlich et al. '771 teach that a bone mineral is useful for implanting in a bone cavity for remodeling, col. 2, lines 52-62. Geistlich '771 also teaches the bone mineral improves strength of the bone at the defect and these implants can be charged with bone cells, col. 3, lines 10-15, 53-56. It would have been obvious to one of ordinary skill in the art to use a bone mineral as taught by Geistlich et al. '771 charged with the chondrocytes in the membrane of Stone in view of Pachence in order strengthen the area of the defect and provide a more natural environment for the cells.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stone '463 in view of Pachence et al. as applied to claim 1 above, and further in view of Seid (5254133). Stone as modified by Pachence et al. is explained supra. However, Stone in view Pachence do not disclose the use of two barrier layers to sandwich the matrix. Seid teaches (Fig. 13) that a coating **76** forms a barrier layer that sandwiches an inner component of the tissue patch. Seid also teaches the coating prevents tissue formation, col. 9, lines 3-8. It would have been obvious to one of ordinary skill in the art to use a barrier layer on both sides of the matrix of Stone as modified by Pachence using the teaching of Seid to inhibit tissue formation prematurely.

Claims 7, 12, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stone et al. (5624463) in view of Pachence et al. as applied to claims 1, 6 above, and further in view of Geistlich et al. (WO 95/18638). Stone as modified by Pachence et al. is explained supra. However, Stone in view Pachence do not disclose a

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pharmaceutical, such as taurolidine or the surface characteristics of the barrier layer and that it is taken from the peritoneum. Geistlich teaches that chemotherapeutics can be used such as taurolidine with a membrane in cartilage repair, page 11, lines 7-10. Geistlich additionally teaches the fibrous side of a membrane provides good adherence properties, page 12. Geistlich also teaches the membrane material can be obtained from the peritoneal membranes of calves, page 12. It would have been obvious to one of ordinary skill in the art to use taurolidine or peritoneal material and have a fibrous portion face the matrix as taught by Geistlich with the method and device of Stone as modified by Pachence such that it therapeutically treats the patient and is from a biological source.

Response to Arguments

Applicant's arguments with respect to claim 1 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-5899. The examiner can normally be reached on Monday-Thursday from 9am to 6:30pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

TC 3700, AU 3738

Brian E. Pellegrino

Brian E. Pellegrino